

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention
[Docket No. CDC-2022-0024]

Proposed 2022 CDC Clinical Practice Guideline for Prescribing Opioids

AGENCY: Centers for Disease Control and Prevention (CDC),
Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC) within the Department of Health and Human Services (HHS), announces the opening of a docket to obtain comment on the proposed clinical practice quideline, CDC Clinical Practice Guideline for Prescribing Opioids - United States, 2022 (the clinical practice guideline). The clinical practice guideline updates and expands the CDC Guideline for Prescribing Opioids for Chronic Pain - United States, 2016, and provides evidence-based recommendations for clinicians who provide pain care, including those prescribing opioids, for outpatients age 18 years and older with acute pain (duration less than 1 month), subacute pain (duration of 1-3 months), or chronic pain (duration of 3 months or more), not including sickle cell disease-related pain management, cancer pain treatment, palliative care, and end-of-life care. The clinical practice guideline includes recommendations for primary care clinicians

(including physicians, nurse practitioners, and physician assistants) as well as for outpatient clinicians in other specialties (including those managing dental and postsurgical pain in outpatient settings and emergency clinicians providing pain management for patients being discharged from emergency departments). This voluntary clinical practice guideline provides recommendations and does not require mandatory compliance; and the clinical practice guideline is intended to be flexible so as to support, not supplant, clinical judgment and individualized, patient-centered decision-making.

DATES: Written comments must be received on or before [INSERT DATE 60 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2022-0024, by either of the following methods.

- Federal eRulemaking Portal:
 http://www.regulations.gov. Follow the instructions
 for submitting comments.
- Mail: National Center for Injury Prevention and Control, Centers for Disease Control and Prevention,
 4770 Buford Highway N.E., Mailstop S106-9, Atlanta, GA
 30341, Attn: Docket No. CDC-2022-0024.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to http://regulations.gov, including any personal information provided. Do not submit comments by email. CDC does not accept comments by email. For access to the docket to read background documents or comments received, go to http://www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: Arlene I. Greenspan,
National Center for Injury Prevention and Control, Centers
for Disease Control and Prevention, 4770 Buford Highway
NE., MS S106-9, Atlanta, GA 30341; Telephone: 770-488-4696.
Email: opioids@cdc.gov.

SUPPLEMENTARY INFORMATION:

Public Participation

Interested persons or organizations are invited to participate by submitting written views, recommendations, and data. Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure.

Comments will be posted on https://www.regulations.gov.

Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your

name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. Do not submit comments by email. CDC does not accept comments by email.

CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign.

Background

In the CDC Guideline for Prescribing Opioids for Chronic

Pain — United States, 2016, CDC communicated the intent to

evaluate and reassess evidence and recommendations as new

evidence became available and to determine when new

evidence would prompt an update. To achieve these aims, CDC

funded the Evidence-based Practice Centers at the Agency

for Healthcare Research and Quality (AHRQ) to conduct

systematic reviews of the scientific evidence in the

following five areas: 1) noninvasive nonpharmacological

treatments for chronic pain; 2) nonopioid pharmacologic

treatments for chronic pain; 3) opioid treatments for

chronic pain; 4) treatments for acute pain; and 5) acute

treatments for episodic migraine. Based upon the new

evidence described in these reviews, an update to the CDC

Guideline for Prescribing Opioids for Chronic Pain - United States, 2016 was warranted.

CDC developed the clinical practice guideline using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) framework, which specifies the systematic review of scientific evidence and offers a transparent approach to grading quality of evidence and strength of recommendations. Recommendations were made based on systematic reviews of the available scientific evidence while considering benefits and harms; patients', caregivers', and clinicians' values and preferences for pain treatment; and resource allocation (e.g., costs to patients or health systems, including clinician time). CDC drafted recommendation statements in the clinical practice quideline focused on assisting clinicians in determining whether to initiate opioids for pain; opioid selection and dosage; opioid duration and follow-up; and assessing risk and addressing potential harms of opioid use.

This clinical practice guideline is voluntary; it provides recommendations and does not require mandatory compliance. It is intended to be flexible to support, not supplant, clinical judgment and individualized, patient-centered decision-making. This clinical practice guideline *is not* intended to be applied as inflexible standards of care

across patient populations by healthcare professionals, health systems, third-party payers, organizations, or governmental jurisdictions. The clinical practice guideline is intended to achieve the following: improved communication between clinicians and patients about the risks and benefits of pain treatment, including opioid therapy for pain; improved safety and effectiveness for pain treatment, resulting in improved function and quality of life for patients experiencing pain; and a reduction in the risks associated with long-term opioid therapy, including opioid use disorder, overdose, and death.

To help assure the clinical practice guideline's integrity, credibility, and consideration of patients', caregivers', and providers' values and preferences, CDC obtained input from patients, caregivers, experts, clinicians, the public, and a federally chartered advisory committee, the Board of Scientific Counselors of the National Center for Injury Prevention and Control (BSC/NCIPC). CDC is also currently obtaining feedback from a panel of external peer reviewers who are experts in topic areas related to opioid prescribing. The panel of external peer reviewers' feedback will be addressed and incorporated into the final clinical practice guideline at the same time that public comments received in response to this Notice are considered.

For more information about the clinical practice guideline or the process of updating it, please visit https://www.cdc.gov/opioids/guideline-update/index.html.

Supporting and Related Material in the Docket

The docket contains the following supporting and related materials to help inform public comment: 1) the draft clinical practice guideline; 2) the GRADE tables; 3) the Opioid Workgroup (OWG) Report, prepared at the request of the BSC/NCIPC and which the BSC/NCIPC unanimously voted to have CDC adopt, and CDC's response to observations outlined in the OWG Report; and 4) an Overview of Community Engagement and Public Comment Opportunities, which describes key themes that emerged about stakeholders' values and preferences regarding pain management, as well as CDC's response to input obtained from these efforts. The GRADE tables include clinical evidence review ratings of the evidence for the key clinical questions. The OWG Report describes the workgroup's findings and observations about the initial draft clinical practice guideline as presented to the BSC/NCIPC at a public meeting on July 16, 2021. The OWG, comprising three BSC/NCIPC members in accordance with federal advisory committee policy, as well as patients with pain, caregivers, and family members of patients with pain, and clinicians and subject matter experts with a variety of relevant pain management expertise, was designed to provide

independent, broad, external, transparent input to the BSC/NCIPC on the diverse and complex issues addressed in the clinical practice guideline. OWG meetings were coordinated by an NCIPC subject matter expert who served as the Designated Federal Official. CDC's response to the OWG Report reflects and describes how CDC incorporated OWG observations and comments in the revised draft of the clinical practice guideline. The Overview of Community Engagement and Public Comment Opportunities document provides a summary of efforts implemented throughout the clinical practice guideline update process to better understand the lived experiences and perspectives of community members that we serve and to ensure additional input from patients, caregivers, clinicians, and the public. CDC's response to the themes and findings that emerged throughout the community engagement and public comment opportunities describes how CDC carefully considered and incorporated diverse perspectives and input from multiple sources and stakeholders into the clinical practice guideline.

Dated: February 7, 2022.

Angela K. Oliver,

Executive Secretary,

Centers for Disease Control and Prevention.

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